Fallopian Tube Catheterization

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Abstract

Fallopian tube catheterization is used for treatment of infertility caused by proximal tubal occlusion, and has replaced surgical treatment for this condition. More recently, fallopian tube catheterization has been used for tubal sterilization. Interventional radiologists tested numerous methods for tubal occlusion using the rabbit as an animal model. As a result, a tubal device has recently been Food and Drug Administration approved for permanent sterilization using hysteroscopic guidance; it can also be placed fluoroscopically by fallopian tube catheterization as an "off-label" procedure. This is a 5-year continuation and update on a procedure that has been done by interventional radiologists for 25 years; history of the development of fallopian tube catheterization in women has been published in detail in this journal. Highlighted in this article will be description of the basic components needed for fallopian tube catheterization.

Keywords
- fallopian tube
- fertility
- sterilization
- interventional radiology

Objectives: Upon completion of this article, the reader will be able to identify the unique anatomy of the fallopian tube, and how interventional radiology techniques can be adapted to opening occluded tubes (well established), and occluding open tubes for sterilization (in its developmental stages).

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Fallopian Tube Anatomy

The fallopian tube is a 7 to 9 cm, elongated trumpet-shaped structure that extends from the cornu of the uterine cavity to the ovary.[1] Its fimbriated end, which is open to the peritoneal cavity, courses over the ovary, allowing the ovulated egg to be pulled into the fallopian tube where fertilization occurs[2] (►**Fig. 1**). The proximal interstitial and isthmic portions closest to the uterus have a luminal diameter of approximately 1 mm, with a straight or slightly curved course in approximately 60%, and a tortuous or convoluted course in approximately 40%. This anatomy is thought to assist in preventing vaginal bacteria from gaining entrance to the body. At the same time, this tiny structure is prone to accumulation of secretions and scarring from inflammation, leading to unwanted sterility.[3,4]

Technique for Tubal Recanalization

The procedure relies on a well-performed accurate hysterosalpingogram (HSG). The contrast agent should be injected slowly under fluoroscopic guidance to avoid sudden intense cramping of the uterus. A condition traditionally called tubal spasm, but poorly understood, can result in temporary proximal tubal obstruction during the diagnostic test.[5,6] If one or both tubes are not visualized, rolling the patient prone, or temporarily deflating the uterine balloon (if that is what was used to fill the uterus), will sometimes result in tubal opacification (►**Fig. 2**).

The equipment and techniques for fluoroscopic fallopian tube catheterization, selective salpingography, and recanalization are extensions of hysterosalpingography and angiography. There are two basic steps to the procedure: (1) uterine access, and (2) fallopian tube access. Uterine access requires

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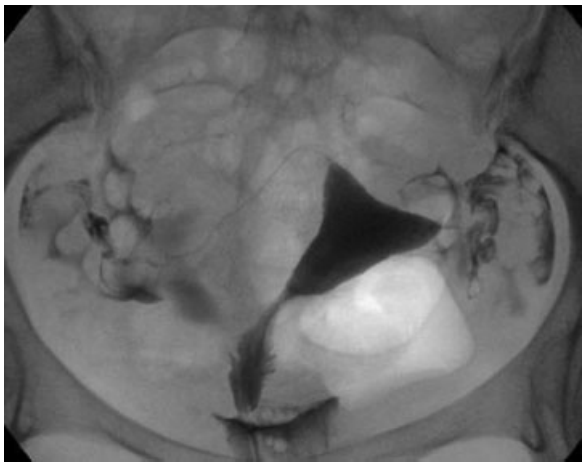

Figure 1 Normal hysterosalpingogram demonstrating patent fallopian tubes.

an HSG device that promotes visualization of the uterine cavity and the tubal ostia, and allows traction to be placed on the cervix for subsequent catheterization. The author's preferred method in the past consisted of gaining access to the uterus with a vacuum cup HSG device (Thurmond-Rosch Hysterocath; Cook Medical, Bloomington, IN).[7] More recently

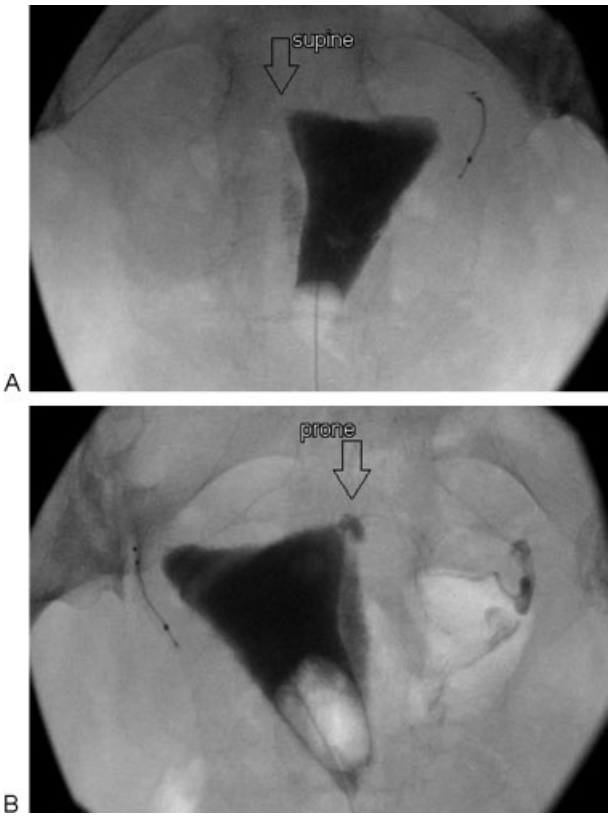

Figure 2 Hysterosalpingogram following hysteroscopic placement of Essure device that was successful on the left side but failed on the right from what the gynecologist called persistent intermittent tubal spasm. (A) Supine position—the right tube appears occluded proximally (arrow). (B) Prone position with 10 minute delayed imaging demonstrates a patent right tube (arrow).

the author has successfully used a 9-Fr balloon catheter (Cook Medical) (►**Fig. 3**). Both of these HSG devices provide a sterile conduit through which a series of coaxial catheters and guidewires can be introduced and allows traction on the uterus without the application of a tenaculum. A conventional HSG with diluted water-soluble contrast medium (Omnipaque 180 mgI/mL or something equivalent) is performed initially, which localizes the uterine cornua without obscuring the catheters.

For fallopian tube access, a coaxial catheter system consisting of a 5 Fr slightly curved polyethylene catheter is advanced over a 0.035-in diameter (0.089 cm) hydrophilic guidewire to the uterine cornu (Cook Medical). The hydrophilic guidewire can be used to gently probe the obstruction.[8] The guidewire is removed, and full-strength contrast agent is injected through the 5-Fr catheter (selective salpingography). The 9-Fr balloon catheter, 5-Fr curved tip catheter, and the 0.035-inch hydrophilic guidewire are available as a kit called the Radiographic Tubal Assessment Kit, or Fluoroset (Cook Medical) (►**Fig. 4**). If proximal tubal obstruction persists, or there is an acute angulation in the fallopian tube, a smaller caliber guidewire-catheter combination can be used. Interventional radiologists usually have their favorites in the 3 Fr size range (►**Fig. 5**). The guidewire and catheter can be advanced as far as necessary to clear the obstruction, usually less than 4 cm from the tubal ostium. When the guidewire passes the obstruction, the guidewire is removed and contrast agent injected through the 3-Fr catheter. Once the recanalization is completed, the 3-Fr catheter is removed, and contrast agent is injected through the 5-Fr catheter still wedged in the tubal ostium to better delineate the tube and visualize the site of recanalization. A postrecanalization HSG can then be performed if desired, however be aware that if both tubes were recanalized, sometimes only the most recently opened tube will opacify, even though both tubes are patent.

The procedure is performed during the follicular phase of the menstrual cycle, utilizing sterile technique and with antibiotic prophylaxis (doxycycline 100 mg orally twice daily for 5 days, ideally starting 2 days before the procedure). A pregnancy test before the procedure is not necessary as long as the procedure is done in the follicular phase of the cycle, similar to the scheduling of a diagnostic HSG. Small doses of intravenous sedation and pain medication may be given, but are usually not necessary. No monitoring is required if conscious sedation is not utilized. It is not necessary to dilate the cervix or give paracervical anesthesia. The patient can usually be discharged within 10 minutes of concluding the procedure and can try to conceive the same week as the procedure.

Complications

Mild uterine cramping and vaginal bleeding usually occur with fallopian tube catheterization. As stated above, intravenous sedation can be used but is usually not necessary. Tubal perforation occurs approximately 2% of the time and is usually related to the severity of underlying tubal disease

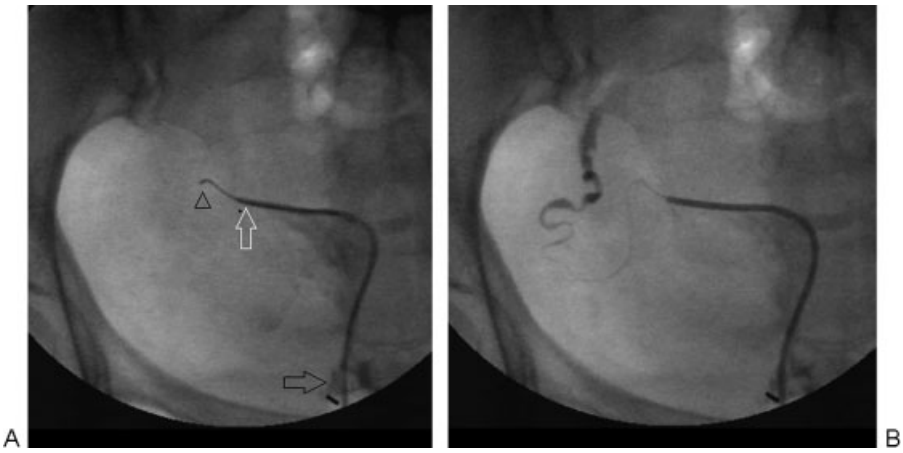

Figure 3 A three component system is used to successfully recanalize the right fallopian tube. (A) 9-Fr balloon catheter is inflated in the cervix (open black arrow), 5-Fr catheter tip is lodged in the tubal ostium (open white arrow), and 0.035" hydrophilic guidewire (arrowhead) is used to dislodge debris causing the proximal tubal obstruction. (B) After removal of the guidewire, contrast agent is injected through the 5-Fr catheter revealing a patent normal tube.

(►**Fig. 6**). No additional monitoring or treatment is necessary when perforation occurs. Usually there is no reason to persist in recanalization attempts after the tube is perforated.

The radiation dose to the ovaries during fluoroscopic catheterization has been documented to be less than 1 rad (10 Gy).[9] The radiation dose varies depending on the equipment and the amount of fluoroscopy used as well as the number of radiographs exposed. A typical procedure takes less than 30 minutes and fluoroscopy time is less than 10 minutes.

Results for Tubal Recanalization

The author prospectively evaluated the therapeutic effect of fallopian tube recanalization in 20 carefully selected patients in whom proximal tubal obstruction was thought to be the primary or sole cause of infertility.[10,11] All patients had documented bilateral proximal tubal obstruction by at least two HSGs and by laparoscopy, with no distal tubal disease identified by laparoscopy. All 20 patients had been recommended for tubal microsurgery or in vitro fertilization (IVF), but underwent catheter recanalization instead. Recanalization of one or both tubes was successful in 19 women (95%).

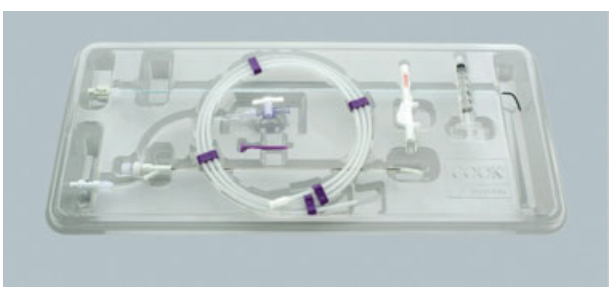

Figure 4 Three components packaged together as the Radiographic Tubal Assessment Kit, or Fluoroset (Cook Medical).

By 1-year postprocedure, 11 of 19 (58%) of the women had conceived without receiving any other therapy, and all pregnancies were intrauterine. In a more heterogeneous group, including women with unilateral obstruction and peritubal adhesions, one may expect a lower short-term intrauterine pregnancy rate in the 20 to 40% range, and approximately 4% tubal pregnancy rate.[11]

The tubal reocclusion rate is difficult to determine because, in part, it is time dependent. In patients who do not conceive by 6 months, it appears that approximately 50% of the tubes are reoccluded.[11] If it is assumed that the tubes are patent in the patients who conceive, this gives an approximate reocclusion rate of 25%. Repeat catheter recanalization is possible, and pregnancies have resulted after the second or even third procedure.

Similar results for complications, tubal patency at the conclusion of the procedure, long-term patency, and pregnancy rates have been reported from around the world.[12]

History of Fallopian Tube Catheterization for Sterilization

In the United States, the most popular method of contraception is tubal ligation.[13] More than 50% of women over the age of 40 have had surgical tubal ligation.[14] Women are willing to undergo the surgical risk, postoperative discomfort, and the expense of the procedure because tubal ligation is reliable and has a cumulative failure rate of only 1.9%.[15] There is a need worldwide for an alternative method of sterilization that is as reliable as the surgical method, but safer and lower in cost.[16]

Attempts to occlude fallopian tubes nonsurgically date back more than 150 years ago when a probe coated with nitric acid was used to sclerose fallopian tubes.[17] Since that time a wide variety of methods for blocking the tubes nonsurgically have been tested. The high failure rate of most agents is attributed to the ability of the fallopian tubes to

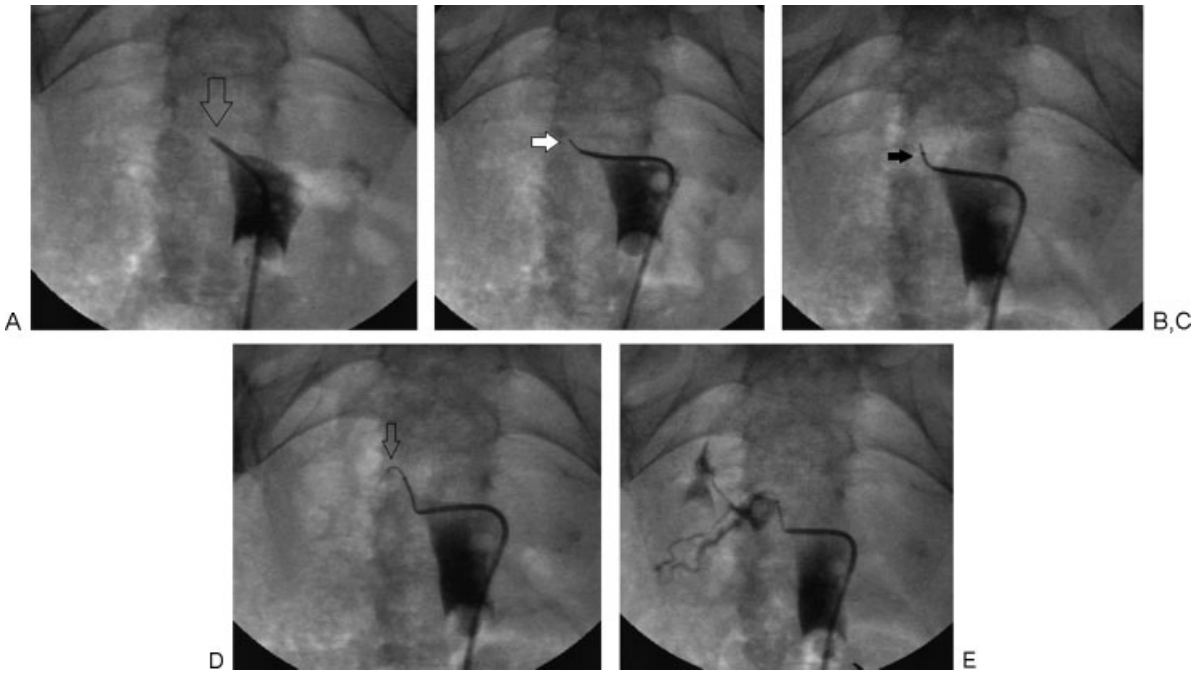

Figure 5 An acute angulation in the tube precluded catheterization (A) 5-Fr catheter is in the tubal ostium (black arrow). (B) The 0.035" hydrophilic guidewire could not be advanced (white arrow). (C) The 0.035" guidewire was exchanged for a 0.015" guidewire with a flexible platinum tip supported by a 3-Fr Teflon catheter (which has a radiopaque bead on its tip—black arrow). (D) The 0.015" guidewire was advanced through the angulated portion of the fallopian tube (arrow). (E) Injection of contrast agent through the 3-Fr catheter reveals a patent tube.

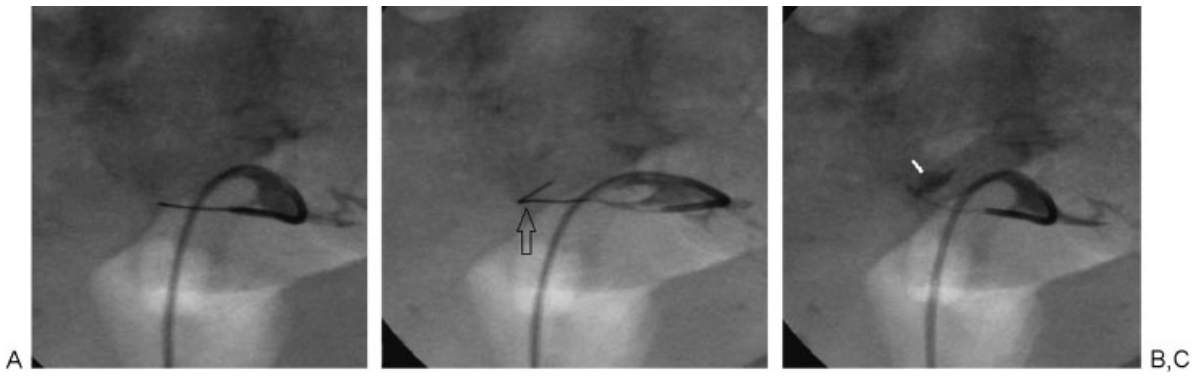

Figure 6 Right tube was perforated during attempt to recanalize a proximal occlusion. (A) 0.035" guidewire used to probe the obstruction. (B) Guidewire advances (arrow). (C) Injection through the 5-Fr catheter reveals contrast agent in the mesosalpinx (arrow) indicative of a contained perforation of the tube at the site of obstruction.

regenerate and recanalize even in the face of extensive tubal damage, and to the difficulty of controlling agents at the time of tubal placement.

Two promising tubal devices were tested in women using the hysteroscope for placement. Formed-in-place silicon plugs underwent clinical trials in the United States in the 1970s,[18–20] and a hydrogel plug with nylon anchors ("P" block) was tested mostly in Sweden in the 1980s.[21] Both of these devices suffered from difficulty in placement due to anatomic factors that could not be overcome by the hysteroscope, and the overall success rate in preventing conception reached only 50 to 82%. Neither of these devices were ever commercially available in the United States.

The development of fluoroscopically guided tubal catheterization in the 1980s offered the opportunity to revisit tubal sterilization methods using an improved delivery system. The author developed an animal model for testing nonsurgical methods of tubal occlusion using New Zealand white rabbits[22–24] (►**Fig. 7**). The fallopian tube of the rabbit is similar to that of a woman and only slightly smaller. Rabbits have two separate uteri, which are elongated and a challenge to catheterize compared with women, however, they provide the opportunity to occlude one fallopian tube attached to its own uterus, and to use the other side as a control. When the rabbit is bred, pregnancies develop in the control uterus but none occur in the side with an effective device.

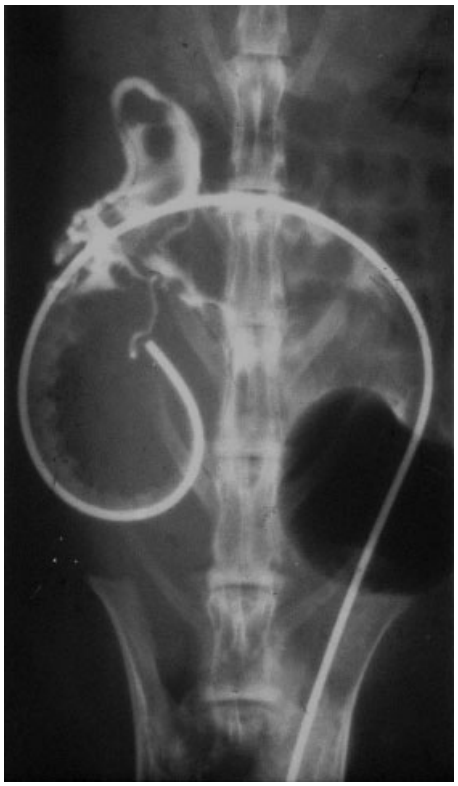

Figure 7 Rabbit fallopian tube catheterized.

Fallopian tube catheterization in rabbits has been used to test several compounds and devices for their contraceptive effect.[25] Berkey et al placed the tissue adhesive (methyl cyanoacrylate [MCA]) in both fallopian tubes of 11 rabbits, which resulted in 100% contraception per cycle.[26] Subsequently, Pelage et al in France had excellent contraceptive results in two women by placing a similar compound, n-butyl-2-cyanoacrylate, into fallopian tubes.[27] However, no American company manufactures these tissue glues because of restrictions on their use by the Food and Drug Administration (FDA).[28]

Metal devices have also been tried. Schmitz-Rode et al placed a spindle-type metal device in the fallopian tubes of 11 rabbits, achieving 82% contraception per cycle.[29] No further testing of this device occurred. Post et al achieved 100% contraception per cycle in nine rabbits using a platinum device designed to span the uterotubal junction[30]; however, clinical trials were not performed.

The author used 14 rabbits to test the prototype of the Essure device (Conceptus, Inc., Leverkusen, Germany), a metal double coil that prevented conception 100% of the time when it remained in the fallopian tube.[31] At the time of necropsy, the Essure was found in 39% of the rabbits in the uterus and not in the fallopian tube. This finding was attributed in part to the difficulty of catheterizing the elongated and tortuous uterus of the rabbit and in part to the design of the device, which was then modified. In the modified device (subsequently tested in women), the outer coil was changed to a dynamically expanding coil made from Nitinol (nickel–titanium alloy) designed to better expand and engage the tubal mucosa. Otherwise the design was the same: 4 cm in length, inner coil stainless steel with Dacron fibers in the midsection. The Dacron fibers were presumed to incite acute inflammation followed by chronic inflammation, fibrosis, and tubal occlusion.[32]

Following review of these rabbit data, the FDA gave approval for initial testing of the Essure device in women. Phase II and phase III international multicenter pivotal trials showed the safety and effectiveness of placement of the Essure device in the fallopian tube using hysteroscopic guidance.[33] The company's decision to pursue FDA approval by hysteroscopic guidance instead of fluoroscopic guidance was based on their intent to market the device to gynecologists. The device became commercially available in Australia in February 2001, and became available in Singapore and Canada. It became commercially available in the United States in November 2002.

It is estimated that as of July 2013, at least 600,000 women worldwide (US, Europe, Australia, New Zealand, Canada, Mexico, and Central and South America) have had Essure devices placed in their fallopian tubes by gynecologists to prevent pregnancies.[34] There are at least two situations where an interventional radiologist may be asked to place a tubal Essure fluoroscopically: a woman who is known in advance to be a poor candidate for hysteroscopy, or when a gynecologist has placed one Essure hysteroscopically and cannot access the second tube. The author has had several referrals for the latter situation (►**Fig. 8**). Because fluoroscopic guidance is fast, easy, and inexpensive when performed by radiologists, this technique will likely gain momentum (Anne Roberts, MD, verbal communication, November 2012).[35]

Technique for Fluoroscopic Tubal Sterilization

The procedure is in the development stages, and has been described by a handful of investigators. The overall technique for gaining access to the uterus and the fallopian tube is the same as already described for treating tubal obstruction. It is assumed that as the fallopian tubes are normal the perforation rate will be less, and the other complications, which are minor, will be the same as those that are well established for fallopian tube catheterization.

The Essure device is 4 cm in length and 0.8 mm in diameter, and comes attached to a delivery catheter (Conceptus, Inc, Mountain View, CA). The delivery catheter will not fit through the 5-Fr catheter in the Radiographic Tubal Assessment Kit. Therefore, once the tubal ostium is engaged with the 5-Fr catheter, the 9-Fr balloon catheter can be advanced over the 5-Fr catheter to the tubal ostium, the 5-Fr catheter removed, and the Essure advanced through the 9-Fr sheath.

Alternatively, one can use the White Lumax 7-Fr catheter (Cook Medical), because the tip is curved and can be more securely advanced into the fallopian tube, and is yet still large enough to accommodate the Essure delivery system. The 7-Fr catheter is advanced into the tubal ostium over the 0.038 inches hydrophilic guidewire and the 5-Fr catheter. The -Fr

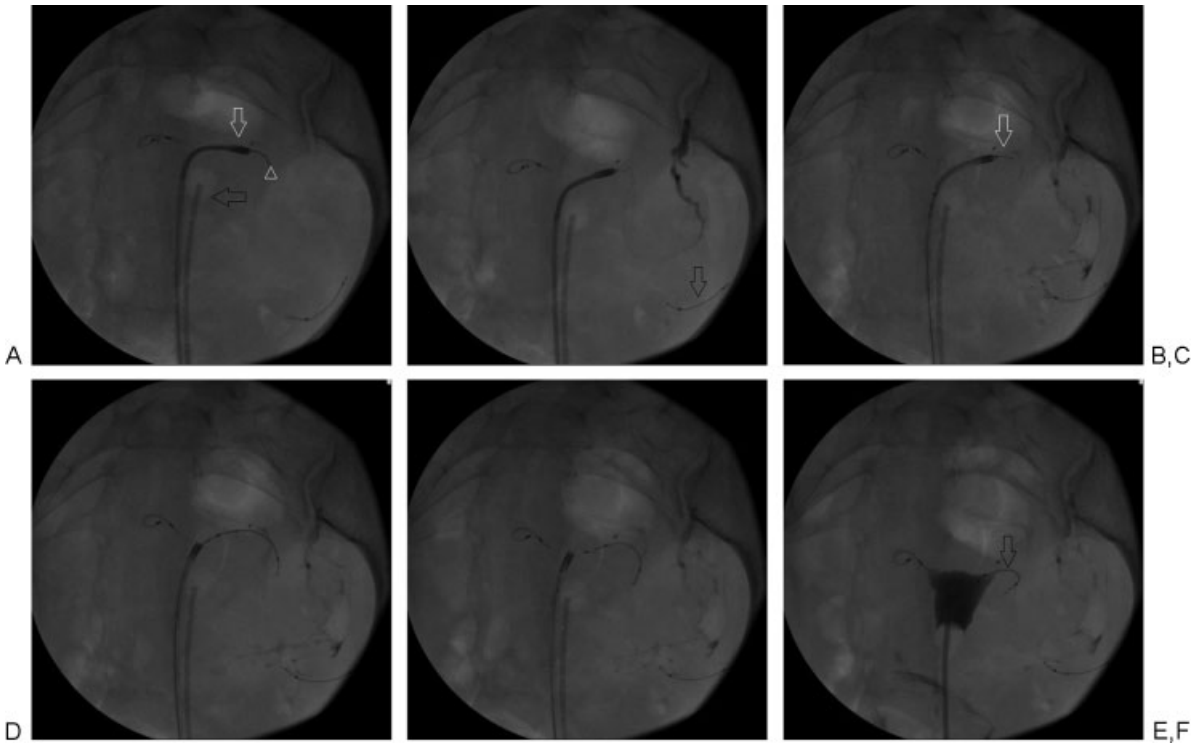

Figure 8 Hysterosalpingogram 3 months after hysteroscopic placement of Essures ("Confirmation Test"; required by the Food and Drug Administration), demonstrates successful tubal occlusion by the right device, however the left device was in the peritoneal cavity and left tube was patent. This patient, a gynecologist, elected fluoroscopic attempt at Essure placement in the left tube. (A) 9-Fr balloon catheter is inflated in the lower uterine segment (black arrow), and a 7-Fr catheter was advanced alongside and into the left tubal ostium (white arrow) with the help of the 0.035" diameter guidewire (arrowhead). (B) Injection confirms the tip of the 7-Fr catheter is in the fallopian tube. Note the inferior migrated left device from prior hysteroscopic placement (arrow). (C) Essure delivery catheter (arrow) is advanced through the 7-Fr catheter. (D) Essure device is advanced into the tube so that no more than 50% trails in the uterine cavity once deployed. (E) Essure device deployed and delivery catheter removed. (F) Contrast agent injected through 9-Fr balloon catheter confirms satisfactory placement of the Essure device (arrow).

catheter and guidewire are removed, and the Essure device is advanced through the 7-Fr catheter into the tube and deployed (►**Fig. 8**).

As with other devices one might use for fallopian tube catheterization, the White Lumax 7-Fr catheter is 80-cm long and designed for vascular use; it needs to be cut with scissors and only the distal 29 cm used.

Current Controversies and Future Directions

It is mandatory to establish a close working relationship with gynecologists and fertility specialists as it is difficult to obtain referrals if gynecologists do not know who you are or do not trust you. Establishing other services that benefit female patients, such as imaging-guided breast biopsies and uterine artery embolization, can be helpful in developing a positive working relationship. Often the first women referred to you will be women with technically challenging anatomy or in whom the gynecologists have given up,[36–38] by helping the gynecologists in these difficult situations, interventional radiologists establish our utility.

In addition, a close working relationship with other specialists is imperative in achieving the patients desired outcome; for a woman whose tubes you have opened, the goal is to have a baby. Once the tubes are open, couples may need additional fertility treatments, which are out of a radiologist's field of expertise.

Fallopian tube catheterization for treatment of proximal tubal occlusion is by now well established. However, the more recently trained fertility specialists are prone to treating most couples with some form of IVF and embryo transfer that bypasses the fallopian tubes altogether. This is because over the past 25 years the "take home baby rate" for IVF has gone from 5% to 75% in some clinics.[39] IVF is still expensive and time consuming, and requires hormonal stimulation and other maneuvers to which some couples object. It is our duty to remind the fertility specialists that catheter recanalization is a relatively inexpensive, minimally invasive treatment for proximal tubal occlusion; articles continue to appear in the reproductive endocrinology literature that advocate it's use before IVF.[39–43]

In contrast to fallopian tube recanalization, fluoroscopically guided occlusion of the fallopian tubes for sterilization is not widely performed, even though it is neither a difficult nor dangerous procedure. Most interventional radiologists are busy enough and not inclined to compete with their gynecologists over this procedure on a day-to-day basis, but rather are content to help them out with the occasional difficult case.

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